



May 24, 2007

David A. Neumann, PhD
Health Policy Analyst,
Maryland Health Care Commission,
4160 Patterson Avenue,
Baltimore, Maryland 21215

**RE: Public Comments Draft regulations, COMAR 10.24.05
Research Waiver Applications for Participation in the
Atlantic CPORT Study of Non-Primary Percutaneous Coronary Interventions
Performed in Maryland Hospitals without On-Site Cardiac Surgery**

Dr. Neumann:

St. Agnes Hospital is pleased to have an opportunity to provide written comments on the draft regulations for participation in the Atlantic CPORT study on non-primary percutaneous coronary interventions. Thank you for the opportunity to continue our participation in the process to explore regulatory options for clinical research to expand access to care for non-primary angioplasty services.

St. Agnes has reviewed the draft regulations in light of the staff's recommendations and offers the following modifications for consideration.:

1. Revise standard 10.24.05.03B(1) such that any hospital in the Metropolitan Baltimore or Metropolitan Washington region that has a waiver (either 1-year or 2-year) to perform primary PCI may apply to participate in the non-primary PCI study.

St. Agnes believes that institutions that have either a 1-year or 2-year waiver have demonstrated sufficient evidence to the Maryland Health Care Commission through the primary PCI application process that the organization has substantially met the rigorous clinical, operational, quality and outcomes standards necessary to safely and efficaciously participate in the study. Further, as noted by several Commissioner's during the initial application process in 2006, additional volume loads from non-primary services will better enable primary PCI programs meet the door-to-balloon time standards.

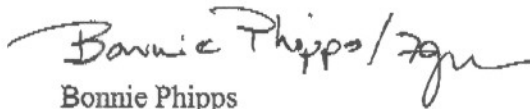
2. Delete standard 10.24.05.04A(3)(a) An applicant's potential to improve the geographic distribution of cardiovascular services.

St. Agnes understands and shares the Commission concerns regarding the distribution of cardiovascular services across the state, particularly the availability of angioplasty services, we believe a preference standard based on geography is premature. Participation in the study should not be a geographic issue. Rather, the goal of the study should be to determine the safety of performing non-primary angioplasty without on-site surgery back-up. To provide the most benefit to the proposed study, St. Agnes believes any preference standards included in the criteria should focus on programs that have the best likelihood of securing necessary volumes and demonstrate the best outcomes. Should the SHP be modified for non-primary angioplasty upon completion of the study, then the establishment of a geographic preference standard may be more appropriate.

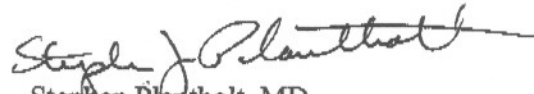
3. As a component of the non-primary study, St. Agnes strongly recommends that the MHCC establish one standard for ALL hospitals that offer angioplasty services for monitoring and reporting operational quality performance at both primary/non-primary PCI waiver sites and those hospitals with on-site cardiac surgery. St. Agnes believes it is to the benefit of all citizens of Maryland to require greater disclosure of angioplasty performance standards for all hospitals regardless of there regulatory status.

Again, St. Agnes appreciates the opportunity to provide comment on the draft regulations that will shape the structure of this clinical study.

Sincerely,



Bonnie Phipps
President/CEO
St. Agnes Hospital



Stephen Platholt, MD
Chief, Cardiology
St. Agnes Hospital